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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/161,122	09/25/1998	HONG JIN	7682-45	7220

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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/161,122	JIN ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 19-28* is/are pending in the application.

4a) Of the above claim(s) *1,3-12,14-17 and 19-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2, 13, 25-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

1. In this application, claims 1-17, and 19-28 are pending. Claims 2, 13, 18, 25, and 26 are pending and under consideration. Claims 1, 3-12, 14-17, and 19-24 have been withdrawn from consideration as to non-elected inventions. An action (the prior action) was mailed in the application on April 21, 2003. In the Response to this action, filed June 30, 2003, the Applicant amended the specification, and claims 2 and 18.

2. Because this action raises new grounds of rejection, it is being made Non-Final.

Specification

3. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994). However, the present application does not share the same disclosure with Application 60/084,153 to which priority is claimed in the amendment to the specification made on June 30, 2003.

It appears that the Applicant intended to claim priority to application 60/084,133

Double Patenting

4. **(Prior Rejection- Maintained)** Claims 2, 13, 18, and 25 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6 and 7 of U.S. Patent No. 5,840,520. The Applicant traverses the rejection on the grounds that "the disclosure or the patent underlying the double patent rejection may not be used as prior art against the claims under consideration." The Applicant argues that because it is improper to look to the teachings of the patent as prior art, and because the claims of the patent make no mention of an RSV comprising the F and G proteins of both RSV A and B, the current claims are distinguished over the patent. This argument is not found persuasive.

The teachings of the 520 patent are not being applied to demonstrate what was known in the art, but to demonstrate the scope of inventions that fall within the claims of the patent, and what would be obvious variations of the claimed inventions. In support of the use of this material, the examiner notes the following excerpt from MPEP section 804:

> When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure.

The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In re Boylan, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in Vogel recognized "that it is most difficult, if not

meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined." Thus, the courts have held that it is permissible to use the specification in determining what is included in, and obvious from, the invention defined by the claim on which the rejection is based. This is true even where elements are drawn from the specification describing the claimed invention, which are not elements in the claim itself. It is therefore proper to read the claims of the patent in light of the specification relating to the claimed invention. The Applicant's argument is traverse is not found persuasive, and because the teachings of the patent relating to the claimed chimeric RSV teach such virus comprising both the F and G proteins of both RSV A and RSV B (col 47, lines 33-36), the rejection is maintained.

5. **(Prior Rejection- Maintained)** Claims 2, 13, 18, and 25 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25, 26, 27, and 32 of copending application 09/923,070. Because the rejection is provisional, the Applicant's have not addressed the rejection. It is therefore maintained.

6. **(Prior Rejection- Withdrawn)** Claim 13 was rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 12 of U.S. Patent No. 5,820,871, and claims 1 and 16 of U.S. Patent No. 5,166,057. In view of the amendment of claim 13 such that it incorporates the limitations of (now cancelled) claim 18, the rejection is withdrawn.

7. **(Prior Rejection- Reformed and Maintained)** Claim 2 was rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over either claims 1 and 12 of U.S. Patent No. 5,820,871, or claims 1 and 16 of U.S. Patent No. 5,166,057, in view of U.S. Patent 6,033,668, issued to Klein et al. The rejection is reformed such that claim 2 is rejected over the indicated claims of either of the 871 or the 057 patents, in view of Klein and of the teachings of any of Beeler et al. (J Virol 63:2941-50 -of record in the March 2000 IDS), Mufson et al. (J Gen Virol 66: 211-24 (1985), or Sullender et al. (Virology 178(1): 195-203). The Applicant traverses the original rejection on the grounds that the patents do not claim RSV chimeric virus, or claim such virus comprising antigens for both RSV A and B, and that Klein does not teach the incorporation of antigens from both RSV A and B into chimeric virus. The first ground of rejection is not found persuasive for substantially the same reasons indicated above with respect to the traversal over the 520 patent.

The Applicant's second ground of traversal is found persuasive with respect to the original rejection over either of the 871 or the 057 patents in view of Klein. However, the additional teachings indicated as lacking from the Klein reference are found in other added references. For example, Heller teaches that successful vaccine design against RSV should

include epitopes reactive against both A and B subtypes. Page 2948. See, also Mufson et al., page 2121; (indicating that an effective anti-RSV immune response would require the presence of at least one F protein, and a G protein from each of the RSV subtypes). Thus, the art renders obvious the inclusion in anti-RSV vaccines or immunogenic compositions of G proteins from each of the RSV subtypes. As each of the 871 and 057 patents indicate that RSV chimeric viruses for use in such compositions fall within the scope of the claimed virus, and as the art renders obvious the inclusion of antigens from both RSV A and B, the invention of claim 2 is an obvious variation of the invention claimed in the indicated patents. Thus, the invention of claim 2 is rejected for obvious type double patenting over the indicated claims of these patent in view of the additional reference cited above.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. **(New Rejection)** Claims 26 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims read on infectious RSV particles comprising deletions of "M2-ORF1 and/or SH-ORF2." It is not clear what is meant by the SH-ORF2 as neither the specification nor the art appears to provide any definition for what is being referred to. The claims are therefore rejected for indefiniteness.

For the purposes of this action, is assumed that the Applicant intended the claim to read on RSV particles wherein the RNA comprises a deletion of M2-ORF1 or M2-ORF 2.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. **(Prior Rejection- Maintained in part)** Claims 2, 13, 18, 25, and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Applicant's argument with respect to claim 13 is persuasive; the rejection is therefore withdrawn against this claim.

However, the rejection is maintained against claims 2, 25, and 26 because, while the Applicant does have support in the application for the RSV with the RNA-directed RNA polymerase binding site of an influenza virus, the Applicant has not demonstrated possession of RSV with binding sites from any virus. The Applicant has provided two examples, both of which are from related negative-stranded RNA virus. Thus, while the Applicant has provided sufficient support for the claimed RSV wherein the polymerase binding site is from either influenza or RSV, the Applicant has not provided sufficient description for embodiments wherein the polymerase binding site may be from any virus.

12. **(New Rejection)** Claims 13, 27, and 28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic compositions comprising a

chimeric RSV, does not reasonably provide enablement for vaccines comprising such a virus. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The claim reads on a vaccine comprising a chimeric RSV comprising an mRNA coding sequence operatively attached to an RSV polymerase binding site, wherein the mRNA encodes the F and G proteins of both RSV-A and RSV-B.

In making a determination as to whether an application has met the requirements for enablement under 35 U.S.C. 112 ¶ 1, the courts have put forth a series of factors. See, In re Wands, 8 USPQ2d 1400, at 1404 (CAFC 1988); and Ex Parte Forman, 230 U.S.P.Q. 546 (BPAI 1986). The factors that may be considered include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. Id. While it is not essential that every factor be examined in detail, those factors deemed most relevant should be considered.

The claims have been described above. It is noted that the Applicant has not demonstrated that the claimed virus are effective vaccines against RSV in humans. It is noted that, in support of the Applicant's claims indicating that the intended use of the virus is as a vaccine, the art recognizes that live attenuated virus may be a good approach to -eventually developing an effective anti-RSV vaccine. Kahn, Curr Opin Pediatr 12(3): 257-62, at 259). However, the art has also long recognized that there are several obstacles to the development of an effective RSC vaccine. See Murphy et al., Virus Res 32: 13-36 (1994- of record in the IDS

filed on April 22, 2003). These difficulties are still present, and still hinder the development of such a vaccine. An acknowledgement of such may be found in the June 2000 article by JS Kahn (supra), which stated that the "prevention of RSV disease continues to be a challenge..." Kahn, at 260 (last paragraph). See also, Crowe, Vaccine 20 (Supp 1): S32-S37 (teaching other obstacles from those in the Murphy article, including difficulties specific to attenuated live vaccines). Each of the Kahn and Crowe references identifies difficulties in developing RSV vaccines that need to be overcome, and careful balances between attenuation and immunogenicity that would be required for an effective live RSV vaccine. Thus, while the Applicant has described that making of attenuated and immunogenic chimeric viruses, the Applicant has not provided an enabling disclosure for an anti-RSV vaccine.

13. **(New Rejection)** Claims 26 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter Rejection. These claims read on the claimed RSV particle wherein the RNA comprises a deletion of SH-ORF2. The does not appear to be written description support for such an embodiment in the originally filed application. The rejected subject matter therefore appears to be New Matter to the application.

Conclusion

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

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